REMARKS

Applicants thank the Examiner for entering claims 92-94 and indicating that they are commensurate in scope with the pending claims.

The Claim Amendments

Applicant has amended claim 85 to recite an antibody concentration of 50 mg/ml instead of 20 mg/ml. See, e.g., page 53, lines 13-18.

The Rejections

1. 35 U.S.C. § 112

(A) **Enablement**

(i) Claims 84, 85 and 94

The Examiner has maintained her rejections of claims 84-85 for alleged lack of enablement. She also has included claim 94 in that rejection. Applicants traverse.

As applicants demonstrated in their previous response, this application provides four different examples of making Infliximab crystals (claims 84 and 94). It also provides examples of making crystals of various other whole antibodies (claim 85). That should be more than enough to satisfy the enablement requirement.

The Examiner, however, argues that the crystal art is "unpredictable" and that the "disclosure of a single species" is not enough. Applicants, however, have done more than required. They have shown by actual example the making of Infliximab crystals in four

different ways and shown by actual example the making of other whole antibody crystals. Even under the Examiner's view of enablement, that is enough.

(ii) Claims 86-91

The Examiner has maintained her rejection of claims 86-91 for alleged lack of enablement. She has also included claims 92 and 93 in this rejection. Applicants traverse.

The Examiner acknowledges that applicants have provided actual examples of the crystallization of two different antibodies and taught that the method is useful for nine other specific antibodies. However, she again argues that this is not enough given the alleged "unpredictability" of crystallization. The Examiner has no support for her position. Applicants have shown that the claimed method works for two antibodies and says that it works for nine others. That meets their burden on enablement. The Examiner needs more than general arguments of "unpredictability" to overcome applicants' specific disclosures. She has not met that burden. She has pointed to nothing that says applicants' specific teachings and examples are not broadly applicable.

(iii) Claims 90 and 91

The Examiner has maintained her rejection of claims 90 and 91 as allegedly lacking enablement. She has also now included claim 94 in that rejection. Applicants traverse.

Again, the Examiner has ignored applicants' specific disclosures. Instead, she relies on general statements about crystallization and buffers. The Examiner also argues that applicants have not specifically shown that the crystallization conditions of any of their four microbatch crystallizations of Infliximab can be used in the claimed large batch crystallization methods. Again, the Examiner ignores the specific teachings of applicants' disclosure and points to nothing but "general crystallization" concerns.

For all of the above reasons, applicants request that the Examiner reconsider and withdraw the enablement rejections.

B. Written Description

The Examiner has maintained her rejection of claims 84 and 85 as allegedly lacking written description. She has also now included claim 94 in this rejection. Applicants traverse.

As with her enablement rejection, the Examiner refuses to accept four actual examples (Infliximab) and several other examples (other antibodies) as showing applicants' possession of the claimed invention. Again, the Examiner relies only on "general" concerns about crystallization. Applicants' specific examples lay to rest those general concerns. Applicants request that the Examiner reconsider and withdrawn this rejection.

2. 35 U.S.C. § 102

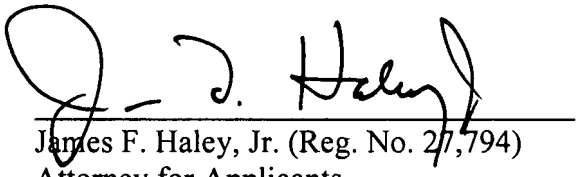
Claim 85 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ely, Biochemistry, 1978, 17(5) 820-23. ("Ely"). Applicants traverse

Applicants have amended claim 85 to recite 50 mg/ml. This overcomes the rejection over Ely.

CONCLUSION

Applicants request reconsideration of this application and the pending claims in view of the foregoing remarks. Early allowance of the pending claims is requested.

Respectfully submitted,



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